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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.



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Stephanie Seidman BELL BOYD & LLOYD L.L.P. 3580 CARMEL MOUNTAIN ROAD SUITE 200 SAN DIEGO CA 91230

In re Application of

BORODY et al

:Decision on Petition

Serial No.: 10/541,528 Filed: 7 July 2005

Attorney Docket No.:119381-00003

This letter is in response to the Renewed Petition under 37 C.F.R. 1.181 filed on 9 June 2008 requesting reconsideration of the restriction requirement dated 15 April 2008.

## BACKGROUND

This application was filed as a national stage under 35 USC 371 and as such, is entitled to PCT unity of invention rules.

On 15 April 2008, the examiner required a restriction between Groups I, II and III, as follows.

Group I, claim(s) 1-11, drawn to a biphasic culture medium.

Group II, claim(s) 13-17, drawn to a kit.

Group III, claim(s) 19-29 and 31-37, drawn to a method of detecting protozoa.

On 28 March 2008 applicants elected Group I, claims 1-11 with traverse.

On 14 April 2008, the examiner considered the traversal and made the lack of unity determination FINAL. Claims 1-11 were rejected under 35 USC 103(a) as being unpatentable over Clark in view of Nakamura.

On 9 June 2008, applicants filed this petition.

## **DISCUSSION**

The file history and petition have been considered carefully.

PCT Rules 13.2 states that:

Where a group of inventions is claimed in one and the same international application, the requirement of unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

The criteria for determining the concept of "contribution over the prior art" is further discussed in Chapter 10 of the International Search and Preliminary Examination Guidelines:

Rule 13.2; Al Annex B, Part 1(b)

10.02 Whether or not any particular technical feature makes a "contribution" over the prior art, and therefore constitutes a "special technical feature," is considered with respect to novelty and inventive step. For example, a document discovered in the international search shows that there is a presumption of lack of novelty or inventive step in a main claim, so that there may be no technical relationship left over the prior art among the claimed inventions involving one or more of the same or corresponding special technical features, leaving two or more dependent claims without a single general inventive concept.

Applicants are correct that the lack of unity determination between the bi-phasic culture media of claim 1 and the kit, which comprises the bi-phasic culture media of claim and further comprises a container containing starch material is improper. Typically a claim directed to a kit comprising a reagent and claim directed to the reagent itself are not separated into separate groups in unity of invention practice. See ISPE Guidelines, Example 15, where claim to a compound shared unity of invention which another claim to the compound and the additional component, "a carrier."

Claim 1: Compound A.

Claim 2: An insecticide composition comprising compound A and a carrier.

Unity exists between claims 1 and 2. The special technical feature common to all the claims is compound A.

Applicants also argue the restriction required between Group I, a product, and Group III, a method of using the product for detection. The petition states that unity exists between the product and process inventions and argues the validity of the rejection made under 35 USC 103(a).

This is not persuasive in view of the first Office action on the merits. PCT Rule 13.2 requires that for unity of invention, the inventions must share a special technical feature which makes as contribution over the prior art. Chapter 10 of the ISPE Guidelines makes it clear that the contribution must be both in terms of novelty, which corresponds to anticipation under US

practice, and inventive step, which corresponds to unobviousness under US practice. The rejection made under 35 USC 103(a) are evidence that the product invention is obvious in view of the prior art.

Upon allowance of all claims directed to the elected product invention, applicant may be entitled to rejoinder of any process claims.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

## DECISION

The petition filed under 37 CFR 1.181 on 14 July 2008 is **GRANTED-IN-PART** as follows:

The request to rejoin Group I, (product) with Group II (kit comprising the product) is **GRANTED**.

The request to rejoin Group I, (product) with Group III (process) is **DENIED**.

The application will be forwarded to the examiner to prepare an Office action consistent with this petition decision which addresses rejoined Groups I and II, claims 1-17.

Any request for reconsideration should be filed within TWO MONTHS of the mail date of this Petition Decision.

Should there be any questions regarding this decision, please contact Special Program Examiner Julie Burke, by mail addressed to Director, Technology Center 1600, PO BOX 1450,

ALEXANDRIA, VA 22313-1450, or by telephone at (571) 272-1600 or by Official Fax at 703-272-8300.

Remy Yucel Director, Technology Center 1600